

REMARKS

Claims 25 and 70 have been amended. New Claims 74-79 have been added. Support for the amendments and new claims is found in the specification and claims as filed.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle and Webber

Claims 25, 26, 28, 29, 63, 64, 68 and 69 were rejected under 35 U.S.C. § 103(a) as obvious over Lebel (US Patent Application Publication No. 2003/0050547) in view of Markle (US Patent No. 5,596,988) and Webber (US Patent No. 6,616,614). It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability..." *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 (C.A.Fed.2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal

conclusion of obviousness"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007).

Applicants respectfully submit that the pending claims as amended are not obvious under 35 U.S.C. § 103(a) for the reasons detailed below.

Pending amended Claim 25, from which Claims 26, 28, 29, 63, 64, 68 and 69 depend either directly or through an intervening claim, recites "[a] small-diameter probe for use with an introducer in a patient having a vessel carrying blood to ascertain characteristics of the blood comprising a cannula having proximal and distal extremities, the distal extremity of the cannula being adapted to be inserted into the vessel of the patient, an oxygen and carbon dioxide sensor assembly disposed in the distal extremity of the cannula for providing an electrical signal when the cannula is disposed in the blood and a connector carried by the proximal extremity of the cannula whereby the distal extremity of the cannula is adapted for slidable travel through the introducer when inserting the cannula into the vessel, the cannula and connector having a size which permits the introducer to be slid off of the proximal extremity of the cannula and the connector after the distal extremity of the cannula has been inserted into the vessel and wherein the sensor assembly comprises at least one insulating layer surrounding a proximal working electrode of a proximal sensor and at least one insulating layer surrounding a distal working electrode of a distal sensor, the proximal sensor comprising a proximal reference electrode and the distal sensor comprises a distal reference electrode, wherein both of said reference electrodes extend at least partially around the at least one insulating layer and wherein the distal working electrode, or a conductor in electrical contact with and extending from the distal working electrode, extends through the at least one insulating layer surrounding the proximal working electrode."

Lebel, Markle and Webber, separately or in any combination, do not disclose, teach, or fairly suggest, among other things, a probe "wherein the sensor assembly comprises at least one insulating layer surrounding a proximal working electrode of a proximal sensor and at least one insulating layer surrounding a distal working electrode of a distal sensor, the proximal sensor comprising a proximal reference electrode and the distal sensor comprises a distal reference electrode, wherein both of said reference electrodes extend at least partially around the at least one insulating layer and wherein the distal working electrode, or a conductor in electrical contact with and extending from the distal working electrode, extends through the at least one insulating

layer surrounding the proximal working electrode" as claimed in the currently amended version of Claim 25. Instead, Lebel teaches a sensing apparatus that includes a sensor lead 12 and a sensor module 20. (Lebel, ¶ 20.) Lebel further teaches that the sensor module 20 includes a flat substrate 30 with a sensing element side 32 and an electronics side 34. The electrodes are deposited onto the substrate. "The electrodes 36 and the electronics on the electronics side 34 of the substrate 30 provide the basis for electrochemical measurement." (Lebel, ¶ 32.) Markle teaches a sequence of sensors mounted in a "desired staggered relationship to reduce the diameter of the catheter." (Markle, column 6, lines 1-9.) Figure 1 of Markle shows an optical fiber pCO₂ sensor 8 staggered with an electrochemical pO₂ sensor 10. With regard to the electrochemical sensor, as shown in Figure 4 of Markle, "the anode 25 is folded into a 'U' shape 27 such that the distal end surface of the anode faces the distal end surface of the cathode." (Markle, column 7, lines 7-19.) Webber teaches an electrode assembly 77 having first and second conductors 81 and 82. With reference to Figure 11 of Webber, the first conductor 81 is covered by an insulating glass. The second conductor 82 is wound in a helix over the first conductor 81. The conductors 81 and 82 extend through a barrier plug 78 that separates a portion of the cannula 51 containing buffer solution 68 from the rest of the cannula 51. (Webber, column 5, lines 30-55.) None of these references, alone or in combination with the others, discloses a proximal working electrode, a distal working electrode, a proximal reference electrode, and a distal reference electrode. Accordingly, no matter how the cited references are combined, these references cannot teach the claimed configuration "wherein both of said reference electrodes extend at least partially around the at least one insulating layer and wherein the distal working electrode, or a conductor in electrical contact with and extending from the distal working electrode, extends through the at least one insulating layer surrounding the proximal working electrode." Thus, a prima facie case of obviousness cannot be established over Lebel and Markle in view of Webber. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Webber, and Schulman

Claim 27 has been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle and Webber, and further in view of Schulman (US Patent No. 5,497,772). The criteria for establishing a *prima facie* case of obviousness are set forth above, as are the limitations of Claim 25, from which Claim 27 depends. Schulman is cited for disclosure related to a glucose

monitoring system, but fails to address the deficiencies of Lebel, Markle, and Webber as discussed above with respect to Claim 25. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Webber, and Cheney

Claims 56-58 and 60-61 have been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle and Webber, and further in view of Cheney (US Patent No. 5,391,250). The criteria for establishing a *prima facie* case of obviousness are set forth above, as are the limitations of Claim 25, from which Claims 56-58 and 60-61 depend. Cheney is cited for disclosure related to thin film sensor fabrication methods, but fails to address the deficiencies of Lebel, Markle, and Webber as discussed above with respect to Claim 25. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Webber, Cheney and Schulman

Claim 59 has been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle, Webber, Cheney, and further in view of Schulman. The criteria for establishing a *prima facie* case of obviousness are set forth above, as are the limitations of Claim 25, from which Claim 59 depends. As discussed above, Schulman merely discloses a glucose monitoring system, but fails to address the deficiencies of Lebel, Markle, Webber, and Cheney as discussed above with respect to Claim 25. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Webber, Cheney and Pantages

Claim 62 has been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle, Webber, and Cheney, and in further view of Pantages (US Patent Application Publication No. 2001/0029337). The criteria for establishing a *prima facie* case of obviousness are set forth above, as are the limitations of Claim 25, from which Claim 62 depends. Pantages is cited for disclosure related to imaging guidewires, but fails to address the deficiencies of Lebel, Markle, Webber, and Cheney as discussed above with respect to Claim 25. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Webber, and Kirsch

Claim 65 has been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle, and Webber, and in further view of Kirsch (US Patent No. 6,503,225). The criteria for establishing a *prima facie* case of obviousness are set forth above, as are the limitations of Claim

25, from which Claim 65 depends. Kirsch is cited for disclosure related to a blood purification device, but fails to address the deficiencies of Lebel, Markle, and Webber as discussed above with respect to Claim 25. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Kirsch, and Webber

Claim 70 has been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle, Kirsch, and Webber. The criteria for establishing a *prima facie* case of obviousness are set forth above. Claim 70 as amended recites "[a] probe for use with an introducer in a patient having a vessel carrying blood to ascertain characteristics of the blood comprising a cannula having proximal and distal extremities, the distal extremity of the cannula being adapted to be inserted into the vessel of the patient, an oxygen and carbon dioxide sensor assembly disposed in the distal extremity of the cannula for providing an electrical signal when the cannula is disposed in the blood, the cannula being made of a gas-permeable material in the vicinity of the oxygen and carbon dioxide sensor assembly, and a connector carried by the proximal extremity of the cannula whereby the distal extremity of the cannula is adapted for slidable travel through the introducer when inserting the cannula into the vessel, the cannula and connector having a size which permits the introducer to be slid off of the proximal extremity of the cannula and the connector after the distal extremity of the cannula has been inserted into the vessel and whereby the oxygen and carbon dioxide sensor assembly is mounted in the distal extremity of the cannula and comprises an electrically insulating conduit having a distal portion, a first working electrode, a second working electrode, a first reference electrode and a second reference electrode, the second reference electrode extending at least partially around the electrically insulating conduit, first, second, third, and fourth conductors extending from the proximal extremity of the cannula to the oxygen and carbon dioxide sensor assembly, wherein the first conductor is electrically coupled to the first working electrode and the second conductor extends through the electrically insulating conduit and is coupled to the second working electrode, the third conductor is electrically coupled to the first reference electrode, and the fourth conductor is electrically coupled to the second reference electrode, the electrically insulating conduit serving as a support for the first reference electrode and as a conduit for the fourth conductor."

Lebel, Markle, Kirsch, and Webber, separately or in any combination, do not disclose, teach, or fairly suggest, among other things, a probe "whereby the oxygen and carbon dioxide

sensor assembly is mounted in the distal extremity of the cannula and comprises an electrically insulating conduit having a distal portion, a first working electrode, a second working electrode, a first reference electrode and a second reference electrode, the second reference electrode extending at least partially around the electrically insulating conduit, first, second, third, and fourth conductors extending from the proximal extremity of the cannula to the oxygen and carbon dioxide sensor assembly, wherein the first conductor is electrically coupled to the first working electrode and the second conductor extends through the electrically insulating conduit and is coupled to the second working electrode, the third conductor is electrically coupled to the first reference electrode, and the fourth conductor is electrically coupled to the second reference electrode, the electrically insulating conduit serving as a support for the first reference electrode and as a conduit for the fourth conductor" as claimed in the currently amended version of Claim 70. Instead, Lebel teaches a sensing apparatus that includes a sensor lead 12 and a sensor module 20. (Lebel, ¶ 20.) Lebel further teaches that the sensor module 20 includes a flat substrate 30 with a sensing element side 32 and an electronics side 34. The electrodes are deposited onto the substrate. "The electrodes 36 and the electronics on the electronics side 34 of the substrate 30 provide the basis for electrochemical measurement." (Lebel, ¶ 32.) Markle teaches a sequence of sensors mounted in a "desired staggered relationship to reduce the diameter of the catheter." (Markle, column 6, lines 1-9.) Figure 1 of Markle shows an optical fiber pCO₂ sensor 8 staggered with an electrochemical pO₂ sensor 10. With regard to the electrochemical sensor, as shown in Figure 4 of Markle, "the anode 25 is folded into a 'U' shape 27 such that the distal end surface of the anode faces the distal end surface of the cathode." (Markle, column 7, lines 7-19.) Kirsch teaches a blood purification device for removing gasses having a housing an microporous hydrophobic hollow fiber members defining a lumen. The hollow fibers are coated with a polymer coating that prevents liquid from penetrating the micropores. The polymer allows dissolved gas to pass out through the pores as a liquid is flowed through the hollow fiber lumen. (Kirsch, column 4, line 35-column 5, line 22.) Webber teaches an electrode assembly 77 having first and second conductors 81 and 82. With reference to Figure 11 of Webber, the first conductor 81 is covered by an insulating glass. The second conductor 82 is wound in a helix over the first conductor 81. The conductors 81 and 82 extend through a barrier plug 78 that separates a portion of the cannula 51 containing buffer solution 68 from the rest of the cannula 51. (Webber, column 5, lines 30-55.) None of these references,

alone or in combination with the others, discloses a first working electrode, a second working electrode, a first reference electrode and a second reference electrode, and first, second, third, and fourth conductors as claimed. Accordingly, no matter how the cited references are combined, these references cannot teach the claimed configuration of "the second reference electrode extending at least partially around the electrically insulating conduit, first, second, third, and fourth conductors extending from the proximal extremity of the cannula to the oxygen and carbon dioxide sensor assembly, wherein the first conductor is electrically coupled to the first working electrode and the second conductor extends through the electrically insulating conduit and is coupled to the second working electrode, the third conductor is electrically coupled to the first reference electrode, and the fourth conductor is electrically coupled to the second reference electrode, the electrically insulating conduit serving as a support for the first reference electrode and as a conduit for the fourth conductor." Thus, a *prima facie* case of obviousness cannot be established over Lebel and Markle in view of Webber. Applicants therefore respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. §103(a) – Lebel in view of Markle, Kirsch, Webber, and Cheney

Claims 71-73 have been rejected under 35 U.S.C. § 103(a) as obvious over Lebel in view of Markle, Kirsch, and Webber. The criteria for establishing a *prima facie* case of obviousness are set forth above, as are the limitations of Claim 70 from which Claims 71-73 depend. Cheney is cited for disclosure related to a gas sensor assembly using a flex circuit, but fails to address the deficiencies of Lebel, Markle, Kirsch, and Webber as discussed above with respect to Claim 70. Applicants therefore respectfully request that the rejection be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history

Application No.: 10/658,926
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shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
12/027,933	PROBE AND DISPLAY HAVING A GAS SENSOR ASSEMBLY AND SURFACE TREATMENT	2/7/2008
12/027,915	PROBE WITH THE GAS PERMEABLE MATERIAL SURROUNDING A GAS SENSOR ASSEMBLY	2/7/2008
12/027,902	SENSOR WITH CONDUCTOR AND SEALING GLASS	2/7/2008
12/027,898	DISPLAY AND PROBE HAVING A REMOVABLE CONNECTIONS	2/7/2008
12/027,905	SENSOR PROBE AND DISPLAY MODULE	2/7/2008
12/172,181	PROBES AND SENSORS FOR ASCERTAINING BLOOD CHARACTERISTICS AND METHODS AND DEVICES FOR USES THEREWITH	7/11/2008
12/172,189	PROBES AND SENSORS FOR ASCERTAINING BLOOD CHARACTERISTICS	7/11/2008

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Application No.: 10/658,926
Filing Date: 09/09/2003

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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